To: Subcommittee on Unauthorized Practice of Law and Artificial Intelligence
From: Wendy Chang
Date: March 26, 2019
Re: B.4. Provider regulation vs. "Legal Advice Device" regulation

In the February 28, 2019 ATILS meeting, there was a thoughtful February 25, 2019 memo from ATILS-OPC staff with a proposal for the concept of focusing the subcommittee's recommendation to the concept of regulatory approval of a "legal advice device" vs. regulatory approval of provider entities. It used as its inspiration the FDA's process for approval of medical devices. This memo provides an analysis of the proposal in the context of the ongoing discussions of the subcommittee.

The FDA Process of "Medical Devices"

The Food and Drug Administration ("FDA") describes its mission, in part, as assuring that "patients and health care providers have timely and continued access to safe, effective, and high-quality medical devices. In addition, it provides consumers, patients, caregivers, and healthcare providers with understandable and accessible science-based information about the products it oversees."[1]

As part of that mission, the FDA has a tiered process for review and authorization of "medical devices" for sale to the general public. "Medical device" is defined as:

> A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is:
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> - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
> - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> - intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.[2]

[1] https://www.fda.gov/medicaldevices/resourcesforyou/consumers/default.htm, last visited March 25, 2019.

[2] *Id.*

Devices are classified according to risk to the public into three classes, with class 1 presenting the lowest risk requiring the lowest level of regulatory review, to level 3, representing the highest risk, and consequently requiring the highest level of review. Levels of review are also separated by levels of risk:

- **Premarket Notification [510(k)]** – submission required to demonstrate that the device is substantially equivalent to a device already placed into one of the three device classifications before it is marketed.
- **Premarket Approval (PMA)** – application required to demonstrate that the device is safe and effective when used. It is the most stringent type of device marketing application and is required for Class III devices.
- **Humanitarian Device Exemption (HDE)** – a marketing application for a Humanitarian Use Device (HUD). An HUD is a medical device that is intended to benefit patients in the treatment or diagnosis of a disease or condition that affects, or is manifested in not more than 8,000 individuals in the United States per year.

  Once approved or cleared, medical devices may be sold to the public.

ATILS-OPC Staff Proposal

The February 25, 2019 memo ("OPC Proposal") presented a proposal for regulatory approval of a "legal advice device", setting forth a proposed structure and a draft flow chart of regulatory approval. Rather than restate the OPC proposal, a copy is attached as Exhibit "A."

Discussion

As will be discussed further below, the structure in the OPC Proposal aligns well with the discussions of the subcommittee to date, and provide a good analog for future discussion.[3]

1. Question for discussion: Does the subcommittee intend for provider certification to apply to the provider for all purposes, irrespective of product offering, or is the contemplated certification providing the safe harbor limited to the provider *as it pertains to the specific approved software*?

   To date, the subcommittee has used language discussing a safe harbor certification process for legal technology providers, but the discussion has appeared to have focused on review of both the actual software product being proposed, as well as a review of the providers themselves, as

[3] Health care and legal services do not directly correlate. Health care utilize a large amount of physical products, some which use technology (for example, a pacemaker) and others that do not (for example, a bandage). Where the product uses technology, such technology is often housed inside a physical product. All of these manifestations meet the FDA's definition of "medical device."

However, there is no equivalent to these physical products in the legal industry. The legal industry's "deliverable" typically consists of some form of words – either spoken or written. In that sense, using the term legal advice "device" may be confusing.

it pertains to the delivery of the software product.[4] Where a company offers more than a single software product, this distinction becomes critical.

If the proposed certification is software specific, then this a direct analog to the OPC Proposal's definition of "legal advice device", which is limited in definition to a form of technology (i.e. software application). ("To oversimplify, staff's concept is that a 'legal advice device' could be defined as any technology that researches and applies law to a person's particular facts and renders a legal opinion on legal question and/or provides a recommendation for action that is legally sound.")[5] In terms of access, developing a process that is physical "device" specific which would only increase costs to members of the public, who would be faced with being required to purchase different devices to operate different programs.

2. Question for discussion: Should the subcommittee propose a tiered regulatory approval process based upon the level of risk to a member of the public?

   The OPC Proposal proffers several tiers of review based upon the FDA process. Please see the OPC Proposal for an illustration of this discussion:

   a. Is it "Legal Advice" – if not, is it a scrivener or legal information provider?

      Under current law, this type of service is defined as not the practice of law. The question is whether or not it makes sense to open a regulatory path for these providers, given the existing law. Is it needed?

   b. Is the product exclusively provided to lawyers/law firms?

      Where a lawyer is using the technology as a tool, then it is not UPL under current law, and the risk of competent and ethical use of the product can be shifted to the lawyer. The question, again, is whether or not it makes sense to open a regulatory path for these providers, given the existing law. Is it needed?

   c. Where a product will be offered (in whole or in part) to members of the public, the level of proof of competency and efficacy required to obtain regulatory approval depends on the degree of risk to the non-attorney user of the product.

      Question for the subcommittee:

      - Is it within public policy to require differing tiers of proof of competency and efficacy?
      - Does creating tiers overcomplicate regulation?
      - Do differing levels of proof create commercial uncertainty for providers?

[4] See Rubin/Walker Memo of February 19, 2019.

[5] OPC Proposal at p.2.

- Who decides what tier a company falls into?
- Would compliance with a uniform standard be easier to administer (with the knowledge that a simpler product with lesser risk would probably have an easier time meeting the uniform standard. Should the decision of what level of proof should be submitted be the choice of the applicant, who then takes the risk of the regulator's decision).

As a predicate question in the OPC Proposal, does the product have an existing regulatory approved version in existence (i.e. 1.0, 2.0, etc.)? If so, the OPC Proposal proffers a streamlined approval process, which would encourage upgrades. This makes logical sense.

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5 categories of risk and the levels of proof as proffered in the OPC Proposal:

Class	Process/Proof[6]
1 – advice re document preparation that does not involve a proceeding before a tribunal (low risk)	Lowest clinical evidence requirement to demonstrate competency and efficacy
2 – advice re issue pertaining to a non-adjudicative proceeding (e.g. a legislative or administrative matter) (moderate risk)	Moderate clinical evidence requirement to demonstrate competence and efficacy
3 – advice re issue pertaining to a civil proceeding before a tribunal (family law or personal injury matter) (high risk)	Higher clinical evidence requirement to demonstrate competence and efficacy
4 – advice re issue pertaining to a criminal proceeding before a tribunal (highest risk)	Highest clinical evidence requirement to demonstrate competence and efficacy

Question to subcommittee: Do we want to adjust the definitions of the different classes to focus on the impact of the services, rather than the type of service being offered.

3. Question to subcommittee: the OPC Proposal sets forth post-approval regulation suggestions to require mandatory self-reporting of complaints received from users, future known issues and material changes in circumstances that impact functionality of the product. Should the subcommittee recommend adoption of this proposal?

[6] The Rubin/Walker memo discussed evaluation metrics at p.8, which is analogous to the clinical trials discussed in the OPC Proposal.